K013541

DEC 1 4 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

1. Device Name :	Magnetic Resonance Imaging Accessory
2. Proprietary Name :	Shoulder Coil
3. Classification :	Class II
4. Establishment Registration #:	1529041
5. Manufacture Facility Location:	USA Instruments, Inc., 1515 Danner Drive, Aurora, Ohio 44202, USA Telephone: 330-562-1000; Fax: 330-562-1422.
6. Performance Standard:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use:	The Shoulder is a receive-only phased array RF coil, used for obtaining diagnostic images of the shoulder and adjacent regions in Magnetic Resonance Imaging systems. The indications for use are the same as for standard MR Imaging. The Shoulder Coil is designed for use with the Rhapsody (1.0Tesla) MRI scanner manufactured by Siemens Medical Systems Inc.
8. Device Description :	The Shoulder Coil consists of two volume RF coil elements in a quadrature design. The elements and associated circuitry are enclosed in a flexible vinyl enclosure housing.

9. Safety and Effectiveness

Shoulder Coil Product Features	Comparison to Predicate Device or other 510(k) Cleared Product
Intended Use Shoulder imaging applications	-Similar to Mark 5000 Phased Array Shoulder Coil manufactured by USA Instruments, Inc. (K983143) - Similar to Phased Array Shoulder Coil manufactured by Medical Advances Inc. (K945778)
Indications for Use Identical to routine MRI imaging	-Similar to Mark 5000 Phased Array Shoulder Coil manufactured by USA Instruments, Inc. (K983143) - Similar to Phased Array Shoulder Coil manufactured by Medical Advances Inc. (K945778)
Coil Enclosure Material Vinyl coated PVC Foam Delrin Acetyl Polyurethane Plastic	-Similar to Mark 5000 Phased Array Shoulder Coil manufactured by USA Instruments, Inc. (K983143) -Similar to Phased Array Shoulder Coil manufactured by Medical Advances Inc. (K945778)
Coil Design Two channel receive-only phased array coil	-Similar to Mark 5000 Phased Array Shoulder Coil manufactured by USA Instruments, Inc. (K983143) - Similar to Phased Array Shoulder Coil manufactured by Medical Advances Inc. (K945778)
Decoupling Switching diode decoupling	-Similar to Mark 5000 Phased Array Shoulder Coil manufactured by USA Instruments, Inc. (K983143) -Similar to Phased Array Shoulder Coil manufactured by Medical Advances Inc. (K945778)
Prevention of RF Burns Does not transmit RF power; decoupling isolates the coil elements from RF fields during RF transmission; coil elements and circuitry are enclosed in a non-conductive housing.	-Similar to Mark 5000 Phased Array Shoulder Coil manufactured by USA Instruments, Inc. (K983143) -Similar to Phased Array Shoulder Coil manufactured by Medical Advances Inc. (K945778)
Radio Frequency Absorption Coil is a receive only coil and does not transmit RF power; power deposition during imaging is limited by SAR algorithm	-Similar to Mark 5000 Phased Array Shoulder Coil manufactured by USA Instruments, Inc. (K983143) -Similar to Phased Array Shoulder Coil manufactured by Medical Advances Inc. (K945778)
Formation of Resonant Loop Decoupling isolates the coil elements from RF fields during RF transmission; length of cable and stiffness does not permit looping	-Similar to Mark 5000 Phased Array Shoulder Coil manufactured by USA Instruments, Inc. (K983143) - Similar to Phased Array Shoulder Coil manufactured by Medical Advances Inc. (K945778)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 4 2001

Mr. Rony Thomas
Vice President,
Marketing and Programs
USA Instruments, Inc.
1515 Danner Drive
AURORA OH 44202

Re: K013541
Trade/Device Name: Shoulder Coil
MRI Specialty Coil
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: October 24, 2001
Received: October 24, 2001

Dear Mr. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013541

Device Name: Shoulder Coil

Indications for Use: The Shoulder Coil is a receive-only phased array RF coil, used for obtaining diagnostic images of the shoulder and surrounding regions in Magnetic Resonance Imaging systems. The Shoulder Coil is designed for use with the Rhapsody (1.0 Tesla) MRI scanner manufactured by Siemens Medical Systems, Inc.

Anatomic Regions: Shoulder and surrounding regions.
Nuclei Excited: Hydrogen

The indications for use are the same as for standard imaging:

The Siemens Rhapsody system is indicated for use as an NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR signal, (2) depend upon NMR parameters (proton density, spin lattice relaxation time T1, spin-spin relaxation time T2) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013541